MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-100919-PIP01-23

Scope of the Application

Active Substance(s)

Bepirovirsen

Condition(s)

Treatment of chronic hepatitis B infection

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

GlaxoSmithKline UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, GlaxoSmithKline UK Limited submitted to the licensing authority on 09/03/2023 11:24 GMT an application for a Paediatric Investigation Plan

The procedure started on 10/07/2023 07:43 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to agree a paediatric investigation plan and grant a deferral and grant a waiver

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100919-PIP01-23

Of 15/08/2023 09:40 BST

On the adopted decision for Bepirovirsen (MHRA-100919-PIP01-23) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for Bepirovirsen, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to GlaxoSmithKline UK Limited, GlaxoSmithKline UK Limited, Middlesex, UNITED KINGDOM, TW8 9GS

ANNEX I

1. Waiver

1.1 Condition:

Treatment of chronic hepatitis B infection The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Solution for injection Route(s) of administration: SUBCUTANEOUS USE Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of chronic hepatitis B infection

2.2 Indication(s) targeted by the PIP:

Treatment of chronic hepatitis B infection

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 2 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 1 (206839) Open label, randomised, controlled study of pharmacokinetics (PK), safety and efficacy of bepirovirsen in children from 2 years to less than 18 years of age with chronic hepatitis B virus (HBV) infection.
Extrapolation, Modeling & Simulation Studies	2	Study 2 Population PK modelling and Exposure-Response study to determine paediatric doses of bepirovirsen for children from 2 years to less than 18 years of age. Study 3 PK bridging/extrapolation of efficacy data to support use of bepirovirsen for treatment of chronic hepatitis B in children aged from 2 years to less than 18 years of age.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	31/05/2034
Deferral of one or more studies contained in the paediatric investigation plan:	Yes